REMARKS

This amendment is responsive to the Office Action mailed on July 25, 2002.

The rejection of claim 4 under 35 USC 112, second paragraph is maintained. It is believed that claim 4 as amended clearly defines what is essential and what is optional. Further support of this amendment can be found at page 23, line 9 of the specification. Thus, this ground of rejection is traversed.

The rejection of claim 31, and 9-10 under 35 USC 102(b) is also maintained for reasons of record. Claims 9, 10, and 31 have been cancelled. Accordingly, this ground of rejection is traversed.

The Examiner has found unpersuasive the applicant's previous argument in relation with the rejection of claims 4, 9-11 and 31-41 under 35 USC 103(a) as being unpatentable over Sharma in view of Kokai and Cloyd et al. It is to be noted that claims 11 and 31of record have been combined together to claim 11 as amended and claims 32 and 37 of record to claim 37 as amended, that claim 41 has been amended and that claims 9, 10, 31-33, 39 and 40 have been cancelled.

As amended, the claims limit the analyte "virus" to a hepatitis C virus (HCV) or hepatitis B virus (HBV) and the probe for detection of a viral antigen to "an antibody", which may specifically react with the virus antigen. Furthermore, the claims are defined so that a detection reaction (reaction between the virus antigen and the probe antibody) is carried out in the presence of a treatment solution without affecting the probe antibody by the treatment solution. In addition, limitations in concentrations of the claimed surfactants have been deleted.

The present invention is characterized in the combined use of an anionic surfactant and another component, as components of a treatment solution to pre-treat a sample containing a hepatitis C virus (HCV) or hepatitis B virus (HBV), followed by

immunoassay using an antibody. In this case, the anionic surfactant disrupts the virus particles of the HCV or HBV and exposes and releases the virus antigen contained in the virus particles. At the same time, as described on page 21, line 17 to 18 of the specification, the anionic surfactant may adversely affect the probe antibody.

According to the present invention, the above-mentioned adverse action of the anionic surfactant is weakened by other components such as amphoteric surfactants, nonionic surfactants and protein denaturants.

In other words, the combination of an anionic surfactant and another components like amphoteric surfactants, nonionic surfactants and protein denaturants provides unexpected advantages that virus particles in a sample are efficiently disrupted, and the virus antigen is efficiently exposed and released and that an adverse affect of the anionic surfactant on the probe antigen is weakened, and as a result, a remarkably high sensitivity for detection of the analyte HCV or HBV, comparing to conventional immunoassays, is established. More specifically, as can be seen from Example 6 on pages 41 and 42 of the specification, the sensitivity (the lower limit of core antigen to be detected) is about 0.5 mU/ml. See page 42, line 5 and Fig. 7. On the other hand, the core antigen 1000 mU/ml corresponds to RNA 100 K copies/ml as shown in Table 7, page 46. Therefore, the above-mentioned 0.5 mU/ml corresponds to "HCV RNA 500 copies". It is well known that the sensitivity of PCR for detection of HCV is about 500 copies of RNA. Thus, the sensitivity of the present invention is comparable with that of PCR. This means that the sensitivity of the immunoassay of the present invention is dramatically higher than the sensitivity of the conventional immunoassay methods for HCV.

Although Sharma describes the use of a non-ionic surfactant, it does not suggest or teach the combined use of the non-ionic surfactant and another surfactant of this invention. In addition and more importantly, Sharma does not suggest or teach that the non-ionic surfactant can weaken or inhibit an adverse effect of an anionic surfactant on a probe antibody.

Kokai describes the combined use of a non-ionic surfactant and protein denaturating agents. However, Kokai does not teach or suggest that the non-ionic surfactant and protein denaturating agents, separately or in combination, weaken or inhibit an adverse effect of an anionic surfactant on a probe antibody.

Cloyd et al. describes treatment of HIV but does not refer to the treatment of HCV or HBV. Since the structure of HIV and that of HCV or HBV are different, the knowledge disclosed in Cloyd is fundamentally different from what disclosed in the present application and cannot be applied to HCV and HBV. In addition, as the Examiner correctly indicated, Cloyd discloses that various agents inactivate the viral antigens in the sample, since they are non-reactive to HIV-specific antibodies. In other words, according to Cloyd, the viral antigens treated with one of various agents including surfactants cannot react with HIV-specific antibodies. The method of present invention uses an HCV or HBV specific antibody as a probe. If the phenomena described in Cloys can be applied to the HCV or HBV, this means that the agents including various surfactants and protein denaturating agents describes in Cloyd cannot be used for the present invention. Furthermore, Cloyd uses an immuno precipitation method to detect immune reaction between the HIV and an anti-HIV antibody. This means that the immune reaction occurs in the absence of the surfactants or other agents. On the other hand, the immune reaction of the present invention is carried out in the presence of a treatment solution containing the claimed surfactants. Thus, the phenomena described in Cloyd cannot be applied to the method of the present invention.

With reasons stated above, Sharma, Kokai and Cloyd separately or in combination do not teach or suggest the present invention and thus this ground of rejection is traversed.

It is believed that claims 4, 11, 34, 37, 38 and 41 as amended with cancellation of claims 9-10, 31-33, 35, 36, 39, and 40 overcome all other grounds of rejection under 35 USC 112. Thus, this ground of rejection is also respectfully traversed.

It is submitted that such claims are in condition for allowance and such action is respectfully requested.

If any fees are necessary in connection with this matter, such fees should be deducted from Deposit Account No. 01-1944.

Respectfully submitted,

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MAILING CERTIFICATE

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Changsik Kim

Date: January 27, 2003

AMENDED CLAIMS

4. (AMENDED) The method according to claim [31] 11, wherein said treatment solution further [contains] comprising at least one of urea[,] and an imidazole ring-containing compound or an indole ring-containing compound.

9. (CANCELLED)

10. (CANCELLED)

11. (AMENDED) [The method according to claim 31, wherein said virus is hepatitis C virus (HCV) or hepatitis B virus (HBV).]

A method for treating a hepatitis C virus (HCV) or hepatitis B virus (HBV) containing sample to obtain a sample suitable for detection of virus by a probe antibody, comprising the steps of:.

(1) treating a virus-containing sample with a treatment solution containing (a) an anionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant, a nonionic surfactant and a protein denaturant; and

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the virus antigen is exposed or released; and antibodies against the virus antigen, if present in the sample, that interfere with a detection reaction, are inactivated, and which sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.

31. (CANCELLED)

32. (CANCELLED)

34. (AMENDED) The method according to claim [32] 37, wherein said treatment solution further contains urea.

35. (CANCELLED)

36. (CANCELLED)

37. [The method according to claim 32, wherein said virus is selected from the group consisting of hepatitis C virus (HCV) and hepatitis B virus (HBV).]

A method for treating a hepatitis C virus (HCV) and hepatitis B virus (HBV)virus containing sample to obtain a sample suitable for detection of virus by a probe antibody, comprising the step of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphophetic surfactant, and (c) an agent selected from the group consisting of a nonionic surfactant and a protein denaturant; and

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and which sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.

38. (AMENDED) The method according to claim [33] 41, wherein said treatment solution further contains urea.

39. (CANCELLED)

40. (CANCELLED)

41. [The method according to claim 33, wherein said virus is selected form the group consisting of hepatitis C virus (HCV) and hepatitis B virus (HBV).]

A method for treating a hepatitis C virus (HCV) and hepatitis B virus (HBV)virus containing sample to obtain a sample suitable for detection of virus by a probe, comprising the step of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphophetic surfactant, (c) a nonionic surfactant and (d) a protein denaturant; and

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and which sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.

AMENDED CLAIMS

4. The method according to claim 11, wherein said treatment solution further comprising at least one of urea and an imidazole ring-containing compound or an indole ring-containing compound.

11. A method for treating a hepatitis C virus (HCV) or hepatitis B virus (HBV) containing sample to obtain a sample suitable for detection of virus by a probe antibody, comprising the steps of:.

(1) treating a virus-containing sample with a treatment solution containing (a) an anionic surfactant and (b) an agent selected from the group consisting of an amphoteric surfactant, a nonionic surfactant and a protein denaturant; and

(2) obtaining a treated virus-containing sample in which the virus particle is disrupted, the virus antigen is exposed or released; and antibodies against the virus antigen, if present in the sample, that interfere with a detection reaction, are inactivated, and which sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.

34. The method according to claim 37, wherein said treatment solution further contains urea.

37. A method for treating a hepatitis C virus (HCV) and hepatitis B virus (HBV)virus containing sample to obtain a sample suitable for detection of virus by a probe antibody, comprising the step of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphophetic surfactant, and (c) an agent selected from the group consisting of a nonionic surfactant and a protein denaturant; and

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and which sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.

38. The method according to claim 41, wherein said treatment solution further contains urea.

41. A method for treating a hepatitis C virus (HCV) and hepatitis B virus (HBV)virus containing sample to obtain a sample suitable for detection of virus by a probe, comprising the step of:

(1) treating a virus-containing sample with a treatment solution comprising (a) an anionic surfactant, (b) an amphophetic surfactant, (c) a nonionic surfactant and (d) a protein denaturant; and

(2) obtaining a virus-containing sample in which the virus particle is disrupted, the viral antigen is exposed or released; and antibodies against the viral antigen, if present in the sample, that interfere with a detection reaction, are inactivated; and which sample is readily subjected to an immunoassay using a probe antibody in the presence of treatment solution.